

AMENDMENTS TO THE CLAIMS

Claims 1-18 (cancelled).

19. (Currently Amended) A method of preparing a gel delivery system comprising gel particles for topical application of at least one active agent, said method comprising:

a) ~~forming a hot~~ an aqueous solution of a polymeric gelling agent, ~~said aqueous solution being maintained at a first temperature above the gelling point of said polymeric gelling agent,~~ the solution being gellable at a lower temperature below the solution temperature, ~~said solution forming a gelling solution, said gelling agent solution having dispersed therein said at least one active agent and a restraining polymer;~~

b) ~~discharging the hot-gelling agent solution through a discharge orifice into a cold-moving stream of hydrophobic liquid and forming droplets of said gelling agent solution, said hydrophobic liquid being at a second temperature below the gelling point of said gelling agent solution, the cold-hydrophobic liquid being immiscible with the gelling agent solution and being at a temperature below the gelling agent gelling point;~~

wherein the gel particles coalesce from the gelling agent solution in the cold hydrophobic liquid stream through the gelling of said droplets, and wherein the restraining polymer has sufficient molecular weight to prevent egress of the restraining polymer from the gel particles, and wherein said restraining polymer is bonded to the at least one active agent in the gelling agent solution so as to retain the at least one active agent in the gel particles.

20. (Currently amended) A method according to claim 19 wherein the ~~cold~~ hydrophobic liquid stream is contained in a conduit, the discharge orifice is located in the conduit and wherein the ~~cold~~ hydrophobic liquid stream moves past the discharge orifice and exerts a force on ~~hot~~ said solution in the discharge orifice, the force acting to withdraw the ~~hot~~ said solution from the discharge orifice.

21. (Currently Amended) A method according to claim 19 comprising discharging the ~~hot~~ gelling agent through an injection tube, the injection tube terminating in the discharge orifice wherein the discharge orifice is positioned in the moving stream of ~~cold~~ hydrophobic liquid.

22. (Currently Amended) A method according to claim 21 comprising containing the ~~cold~~ hydrophobic liquid stream in a conduit wherein the liquid stream flows through the conduit and wherein the injection tube extends into the conduit.

23. (Previously Presented) A method according to claim 22 wherein the conduit has a rectilinear portion and the injection tube extends approximately perpendicularly into the rectilinear portion of the conduit.

24. (Previously Presented) A method according to claim 22 wherein the conduit has a cross-sectional area of from about 4 to about 100 times the cross-sectional area of the injection tube, optionally at least 25 times.

25. (Currently Amended) A method according to claim 22 wherein the ratio of the flow rate of the ~~hot~~ gelling agent solution to the flow rate of the ~~cold~~ hydrophobic liquid is between about 1:2 and 1: 50.

26. (Previously Presented) A method according to claim 22 wherein the injection tube has an internal diameter of from about 0.05 to about 10 mm.

27. (Currently Amended) A method according to claim 22 wherein the conduit has a cross-sectional area of from about 4 to about 400 times the cross-sectional area of the injection tube, the ratio of the flow rate of the ~~hot~~ gelling agent solution to the flow rate of the ~~cold~~ hydrophobic liquid is between about 1:2 and 1: 50 and the injection tube has an internal diameter of from about 0.05 to about 10 mm.

28. (Previously Presented) A method according to claim 22 comprising cooling the hydrophobic liquid upstream of the discharge orifice.

29. (Previously Presented) A method according to claim 28 comprising separating the gel particles from the hydrophobic liquid and recirculating the hydrophobic liquid to the discharge orifice.

30. (Currently Amended) A method according to claim 19 wherein the ~~cold~~ hydrophobic liquid stream is contained in a conduit, the ~~hot~~ gelling agent is discharged through an injection tube and the injection tube terminates in the discharge orifice, the discharge orifice being located in the conduit and wherein the ~~cold~~ hydrophobic liquid stream moves past the discharge orifice and exerts a force on ~~hot~~ solution in the discharge orifice, the force acting to withdraw the ~~hot~~ solution from the discharge orifice.

31. (Previously Presented) A method according to claim 30 wherein the gel particles are capable of being manually crushed and applied topically by an end user.

32. (Previously Presented) A method according to claim 30 wherein the gelling agent comprises a pH stable water-soluble polymer optionally selected from the group consisting of synthetic polymers, vinyl polymers and copolymers, acrylamide polymers and copolymers, natural polymers, polysaccharides, proteins, synthetically modified polysaccharides, synthetically modified proteins, botanically derived gels and carbopol.

Claim 33. (Cancelled)

Claim 34. (Cancelled)

Claim 35. (Cancelled)

Claim 36. (Cancelled)

37. (Currently Amended) A method according to claim 19 comprising pumping the ~~hot~~ gelling agent solution from a heated vessel containing a bulk supply of the ~~hot~~ gelling agent solution to the discharge orifice.

38. (Currently Amended) A method according to claim 37 comprising recirculating the ~~cold~~ hydrophobic liquid through a cooled tank.

39. (Previously Presented) A method according to claim 38 comprising recirculating a coolant between a chiller and the cooled tank to maintain a desired low temperature in the tank.

40. (Previously Presented) A method according to claim 37 comprising flowing the hydrophobic liquid containing gel particles over a screen to separate the gel particles from the hydrophobic liquid.

41. (Currently Amended) A method according to claim 19 comprising pumping the ~~hot~~ gelling agent solution from a heated vessel containing a bulk supply of the ~~hot~~ gelling agent solution to the discharge orifice, recirculating the ~~cold~~ hydrophobic liquid through a cooled tank, recirculating a coolant between a chiller and the cooled tank to maintain a desired low temperature in the tank and flowing the hydrophobic liquid containing gel particles over a screen to separate the gel particles from the hydrophobic liquid.

42. (Currently Amended) A method according to claim 19 comprising selecting the discharge size of the discharge orifice and the velocity of the moving stream of ~~cold~~ hydrophobic liquid according to the desired gel particle size.

43. (Currently Amended) A method according to claim 19 wherein the flow rate of the ~~cold~~ hydrophobic liquid is greater than the flow rate of the gelling agent solution.

44. (Currently Amended) A method according to claim 19 comprising discharging the gelling agent solution into the cold hydrophobic liquid stream at a flow rate of from

about 2.5 to 6.2 ml/min wherein the ~~cold~~ hydrophobic liquid stream moves with a flow rate of from about 10 ml/min to about 300 ml/min.

45. (Previously Presented) A method according to claim 19 operated to make beads of from about 2.8 to about 4 mm diameter or from about 0.4 to about 0.7 mm diameter.

46 (Cancelled)

47. (Withdrawn) Apparatus according to claim 65 comprising an injection tube for injecting the hot gelling agent solution into the cold liquid stream, the injection tube being terminated by the discharge orifice, the discharge orifice being located in the cold liquid conduit so that movement of the cold hydrophobic liquid past the discharge orifice draws the hot gelling agent solution through the discharge orifice.

48 (Withdrawn) Apparatus according to claim 47 wherein the cold liquid conduit has a rectilinear portion and the injection tube extends approximately perpendicularly into the rectilinear portion of the conduit.

49. (Withdrawn) Apparatus according to claim 65 wherein the internal diameter of the cold liquid conduit is greater than the internal diameter of the injection tube, optionally

from about 4 to about 400 times the cross-sectional area of the injection tube or, optionally also, at least 25 times the cross-sectional area of the injection tube.

50. (Withdrawn) Apparatus according to claim 65 operable so that the ratio of the flow rate of the hot gelling agent solution to the flow rate of the cold hydrophobic liquid is between about 1:2 and 1:50.

51. (Withdrawn) Apparatus according to claim 65 wherein the injection tube has an internal diameter of from about 0.05 to about 10 mm, optionally about 0.8 mm.

52. (Withdrawn) Apparatus according to claim 65 comprising an injection tube for injecting the hot gelling agent solution into the cold liquid, the injection tube being terminated by the discharge orifice, the discharge orifice being located in the cold liquid conduit for the cold hydrophobic liquid stream to move past the discharge orifice and draw the hot gelling agent solution through the discharge orifice wherein the cold liquid conduit has a rectilinear portion and the injection tube extends approximately perpendicularly into the rectilinear portion of the conduit wherein the internal diameter of the cold liquid conduit is greater than the internal diameter of the injection tube from about 4 to about 400 times the cross-sectional area of the injection tube, and wherein the ratio of the flow rate of the hot gelling agent solution to the flow rate of the cold hydrophobic liquid is between about 1:2 and 1:50.

53. (Withdrawn) Apparatus according to claim 65 wherein the cold liquid source comprises a chiller to cool the hydrophobic liquid upstream of the discharge orifice.

54. (Withdrawn) Apparatus according to claim 53 comprising a cooled reservoir of the hydrophobic liquid wherein the chiller coupled with the cooled reservoir to cool hydrophobic liquid therein.

55. (Withdrawn) Apparatus according to claim 54 wherein the reservoir comprises tank and the cold hydrophobic liquid can be recirculated through the cooled tank.

56. (Withdrawn) Apparatus according to claim 65 comprising a separator to separate the gel particles from the hydrophobic liquid the separator being connected with the cold liquid source for recirculation to the discharge orifice of hydrophobic liquid received from the separator.

57. (Withdrawn) Apparatus according to claim 56 wherein the separator comprises a screen.

58. (Withdrawn) Apparatus according to claim 55 comprising a separator to separate the gel particles from the hydrophobic liquid the separator being connected to deliver hydrophobic liquid to the cooled tank for recirculation to the discharge orifice.

59. (Withdrawn) Apparatus according to claim 65 wherein the hot liquid source comprises a heated vessel containing a bulk supply of the hot gelling agent solution.

60. (Withdrawn) Apparatus according to claim 59 wherein the heated vessel is jacketed for insulation and comprises a mixer.

61. (Withdrawn) Apparatus according to claim 65 wherein the apparatus comprises a pump to pump the hot gelling agent solution from the heated vessel to the discharge orifice.

62. (Withdrawn) Apparatus according to claim 65 wherein the hot liquid source comprises a heated vessel containing a bulk supply of the hot gelling agent solution, the cold liquid source comprises a cooled tank of hydrophobic liquid and the apparatus comprises:

e) a pump to pump the hot gelling agent solution from the heated vessel to the discharge orifice;

f) recirculating apparatus to recirculate the cold hydrophobic liquid through the cooled tank;

g) a chiller to cool the cooled tank;

h) a screen to separate the gel particles from the hydrophobic liquid; and

i) flow-directing apparatus direct the flow of hydrophobic liquid containing gel particles over the screen to separate the gel particles from the hydrophobic liquid.

63. (Cancelled)

64. (Previously Presented) Gel beads produced by a method according to claim

19.

65. (Withdrawn) Apparatus performing the method of claim 19 comprising:

a) a hot liquid source of a hot aqueous solution of a gelling agent, the solution being gellable at a temperature below the solution temperature.

b) a cold liquid conduit carrying a cold moving stream of hydrophobic liquid the cold hydrophobic liquid being immiscible with the gelling agent solution and being at a temperature below the gelling agent gelling point;

c) a discharge tube having a discharge orifice and discharging the hot gelling agent solution through the discharge orifice into the cold moving stream of hydrophobic liquid in the conduit;

wherein the gel particles coalesce from the gelling agent solution in the cold hydrophobic liquid stream.

66. (New) The method of claim 19, wherein the restraining polymer is ionically bonded to the at least one active agent.

67. (New) The method of claim 66, wherein said first temperature ranges from between about 70°C and about 100°C.

68. (New) The method of claim 66, wherein said second temperature is below about 30°C.

69. (New) A method of preparing a gel delivery system comprising gel particles for topical application of at least one active agent, said method comprising:

a) forming an aqueous solution of a polymeric gelling agent, the solution being gellable at a temperature below the solution temperature, said aqueous solution having a temperature ranging from between about 70°C and about 100°C; said solution forming a gelling solution, said gelling agent solution having dispersed therein said at least one active agent and a restraining polymer;

b) discharging the gelling agent solution through a discharge orifice into a ~~cold~~ moving stream of hydrophobic liquid and forming droplets of said gelling agent solution, the ~~cold~~ hydrophobic liquid being immiscible with the gelling agent solution and being at a temperature below about 30°C, said temperature below the gelling agent solution gelling point;

wherein the gel particles coalesce from the gelling agent solution in the ~~cold~~ hydrophobic liquid stream through the gelling of said droplets, and wherein the restraining polymer has sufficient molecular weight to prevent egress of the restraining polymer from the gel particles, said restraining polymer being ionically bonded to the at least one active agent in the gelling agent solution so as to retain the at least one active agent in the gel particles.

70. (New) A gel delivery system, comprising gel particles for topical application of at least one active agent produced according to the method of claim 19.